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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/967,267 10/27/92 COOK

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P ~~ISIS-0710~~
EXAMINER

KUNZ, G

ART UNIT

PAPER NUMBER

1211

DATE MAILED:

05/16/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined ☒ Responsive to communication filed on 12/26/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892. 2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449. 4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474. 6. ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 9-10 & 15-25 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 9-10 & 15-25 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

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PTOL-326 (Rev. 2/93)

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1211.

Claims 9 - 10 and 15 - 25 are pending in the case.

Any 35 USC statutes not cited in this Office action can be found cited in full in a previous Office action.

The rejection of claim 9 - 10 and 15 - 25 are rejected under 35 USC 103 as being obvious over Cotten et al. and Iribarren et al. in view of Wagner et al. has been withdrawn in view of applicant's showing that they were in possession of the part of the invention taught by Wagner et al. (i.e., 2'-O-ethyl guanosine) prior to the publication of Wagner et al.

The rejection of claims 15 and 16 under 35 USC 112, first paragraph, because of lack of written description, i.e., new matter, has been withdrawn in view of applicant's argument that there is adequate written description for the limitations of claims 15 and 16 on page 12 of the disclosure.

The rejection of claims 9 - 10 and 15 - 16 under 35 USC 112, first paragraph, because of a lack of enablement placing an undue burden on the person wanting to make and use the invention has been withdrawn in view of applicant's arguments.

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Claims 9 - 10 and 15 - 25 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to 2'-O-substituents which do not contain the exceptionally bulky groups such as carbocycles, heterocycles, and aryl groups. The person of ordinary skill in the art would not accept that bulky 2'-O-substituents, particularly those close to the 2'-oxygen and attached to each ribose moiety in a polynucleotide would yield a probe that could reasonably be expected to hybridize effectively. Furthermore, the disclosure provides no guidance with regard to how long a straight chain tether must be to properly accommodate a polycyclic structure. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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Claims 9 - 10 and 15 - 25 are rejected under 35 U.S.C. § 103 as being unpatentable over Buhr et al. (5,466,786).

Claims 9 and 15 - 22 are directed to guanosine derivatives wherein the 2'-O- position is substituted with a hydroxyl- or thio-containing alkyl group having 3 - 20 carbon atoms (n is at least 1). Claims 9 - 15 - 22 are also directed to oligomers containing 2'-O-substituted nucleosides.

Buhr et al. discloses a genus of 2'-O-substituted nucleosides wherein the substituent is substituted or unsubstituted alkyl, substituted or unsubstituted alkenyl having 2 - 20 carbon atoms, or substituted or unsubstituted aryl of 6 - 20 carbon atoms. These alkyl, alkenyl, and aryl groups may be substituted with hydroxyl, amino, or thiol (**claim 8**). Buhr et al. also discloses 2'-O-ethyl and 2'-O-butyl substituents at column 13, lines 53 - 67. Buhr et al. further teaches that these 2'-O-modifications confer nuclease resistance upon polynucleotides (column 2, lines 38 - 43). Buhr et al. further teach that a phosphate group or a some] conventional protecting group may be attached at either the 5'-OH and/or the 3'-OH positions.

Therefore, the claimed 2'-O-substituted guanosine derivatives would have been obvious to the person of ordinary skill in the art at the time of the invention wanting to make a polynucleotide resistant to nuclease digestion.

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Thus, the invention is prima facie obvious in the absence of clear and convincing evidence to the contrary.

Claims 10 and 23 - 25 are rejected under 35 U.S.C. § 103 as being unpatentable over Buhr et al. (5,466,786) in view of Kikuchi et al. (Chem. Abstract No. 110: 24228).

The claims are directed to 2'-O-modified-2-aminoadenosine derivatives and oligomers containing same.

The teachings the Buhr et al. patent are set forth above. Buhr et al. does not specifically disclose 2'-aminoadenosine as a substitute base for adenosine in a polynucleotide.

However, Kikuchi et al. teach that 2'-aminoadenosine can be substituted for adenosine in an oligonucleotide with the a slight increase in melting temperature and a resistance to RNase T2 and nuclease P1 digestion.

Therefore, the person of ordinary skill in the art at the time of the invention would have found it obvious to have substituted 2-aminoadenosine for adenosine in the 2'-O-substituted oligonucleotides of Buhr et al. as taught by Kikuchi et al. for the purpose of gaining an increase in melting temperature and a resistance to RNase T2 and nuclease P1. Thus, the invention is prima facie obvious in the absence of clear and convincing evidence to the contrary.

Claims 9 - 10 and 15 - 25 are provisionally rejected under the judicially created doctrine of obviousness-type doublepatenting as being unpatentable over claims 1 - 8,

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62 - 63 and 69 72 of copending application Serial No. 08/373,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each claim 2'-O-substituted monomers and oligomers which overlap with one another.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in second patent not patentably distinct from claim in a first patent. In re Vogel, 164, USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application is shown to be commonly owned with this application. See 37 CFR 1.78(d).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kight, can be reached on (703) 308-0204. The fax phone number for this Group is (703) 305-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Gary L. Kunz, Ph.D.
May 9, 1996

Gary L. Kunz
GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1800
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